DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

91582d

July 30, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 70

Terry Hoff
Chief Executive Officer
Unimed Physician's Complex
One Burdick Expressway West
Minot, North Dakota 58701

Dear Mr. Hoff:

We are writing to you because on July 25, 2001, your facility was inspected by a representative of the State of North Dakota acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following non-compliance at your facility:

Level 1 Non-Compliance

1. Failure to produce documents verifying that interpreting physician [redacted] met the initial requirement of being certified in the appropriate specialty by a FDA-approved board or having two months of initial training in the interpretation of mammograms prior to April 28, 1999.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed) which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

Level 2 Non-Compliances

2. Medical audit and outcome analysis was not performed annually at Unimed Physician's Complex.

3. Medical audit and outcome analysis was not done separately for each Interpreting Physician at Unimed Physician's Complex.

4. Medical audit and outcome analysis was not done for the facility as a whole at Unimed Physician's Complex.

5. Failure to produce documents verifying that interpreting physician [redacted] met the initial experience requirement of having interpreted or multi-read 240 mammograms in six months.

6. Failure to produce documents verifying that Radiologic Technologist [redacted] met the initial requirement of having 40 contact hours training specific to mammography.

7. Failure to produce documents verifying that interpreting physician [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

8. Failure to produce documents verifying that interpreting physician [redacted] met the initial requirement of having 40 hours of medical education in mammography prior to April 28, 1999.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

Please submit your response to Compliance Officer Thomas P. Nelson, 240 Hennepin Avenue, Minneapolis, MN 55401.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http://www.fda.gov*.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Nelson at (612) 334-4100 ext. 177.

Sincerely,

James A. Rahto
Director
Minneapolis District

TPN/ccl

Enclosure: MQSA Facility Inspection Report, 7/26/01

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